Effectiveness of Covaxin and Covishield in Reducing Severe COVID-19 Among Hospitalized Patients in India

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Abstract

Introduction: COVID-19 is among the most devastating diseases. Worldwide, numerous vaccines were created to prevent and manage the virus. However, the frequent mutation of SARS-CoV-2 variants has led to concerns about the effectiveness of commonly used vaccines in preventing severe disease in the Indian population. This study aimed to assess the effectiveness of the BBV152 (Covaxin) and ChAdOx1-S (Covishield) vaccines in preventing severe forms of COVID-19. Materials and Methods: This retrospective study utilized hospital records and included 204 vaccinated COVID-19 patients selected through consecutive sampling. Information on vaccination status, comorbidities and CT severity scores from HRCT lung reports was extracted from patient case sheets. Fisher's exact test and binomial logistic regression analysis were used to determine the independent associations of various factors with the dependent variables. Results: Out of 204 records, 57.5% were males with a mean age of 61.8 ± 9.8 years. The study demonstrated that both vaccines provide effective protection against severe illness (90.2%), with BBV152 showing superior efficacy compared to ChAdOx1-S. Further more, male gender, partial vaccination, presence of comorbidities, and the specific type of vaccine administered were identified as independent factors predicting severe lung involvement. Conclusions:This study reveals that both vaccines were highly effective (90%) in preventing severe COVID-19 in fully vaccinated individuals. When comparing the two vaccines, BBV152 showed a slightly higher effectiveness than ChAdOx1-S in preventing severe illness of COVID-19.

Key-words: *COVID-19 vaccination, CT severity scores, and the aged population*

1. INTRODUCTION

COVID-19 has emerged as a highly impactful infectious disease. The World Health Organization declared it a pandemic on March 11, 2020 [1], leading to substantial global mortality, morbidity, and socio-economic disruptions [2]. Efforts worldwide have focused on developing safe and effective vaccines to combat COVID-19, with approximately 13 vaccines approved by the WHO under Emergency Use Authorization [3]. In India, 12 COVID-19 vaccines have been authorized, with the Whole Virion Inactivated BBV152 (COVAXIN®) and the recombinant ChAdOx1-S (COVISHIELD™) being prominently administered to adults [4]. COVAXIN is developed by Bharat Biotech in collaboration with the Indian Council of Medical Research, while COVISHIELD is produced by the Serum Institute of India, based on technology from the University of Oxford [5,6].

Initially, ChAdOx1-S was reported to have an efficacy of 85% against moderate to severe illness, while BBV152 showed 93.4% efficacy against severe COVID-19 [5,6]. However, concerns have arisen due to the continuous mutation of SARS-CoV-2 variants, potentially affecting vaccine effectiveness [7,8]. Against the Delta variant (B.1.617.2), BBV152 and ChAdOx1-S vaccines have demonstrated reduced effectiveness at 65.2% and 70.4%, respectively [9,10]. Against this backdrop, the current study aimed to evaluate the effectiveness of COVAXIN and COVISHIELD in preventing severe COVID-19 using HRCT lung reports among vaccinated patients admitted during the second wave to a designated COVID-19 hospital

2. MATERIALS AND METHODS:

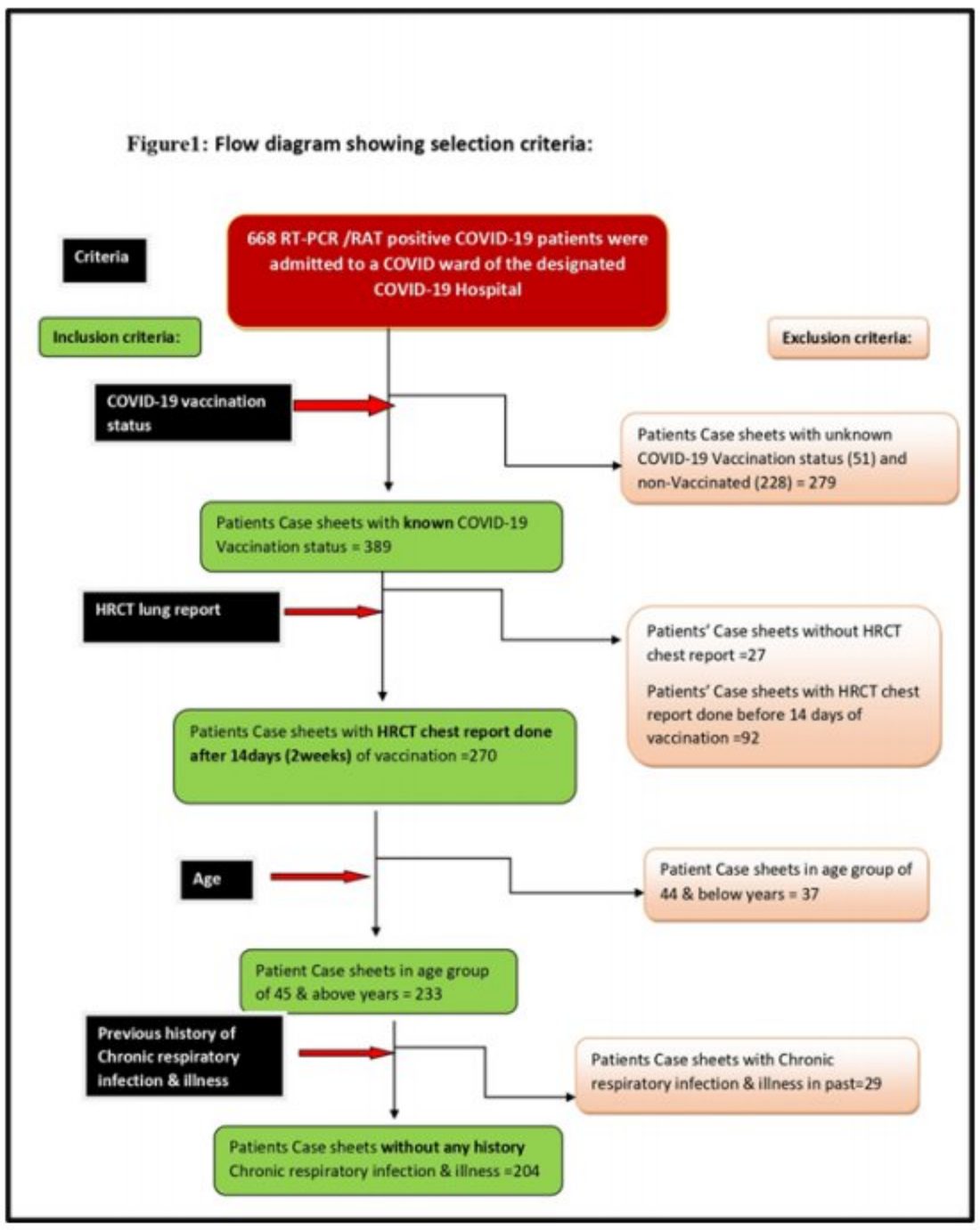
2.1 Study design and setting:

This retrospective study was conducted among COVID-19 patients admitted to a designated COVID-19 centre in southern India, between April 1, 2021, and July 31, 2021, utilizing hospital records.

2.2 Selection criteria:

The study reviewed records of COVID-19-positive patients admitted during the specified period. It included patients aged 45 years and above who had undergone High-Resolution Computed Tomography (HRCT) lung scans, tested positive for the virus via RT-PCR within 14 days of COVID-19 vaccination, and received treatment for symptoms in the hospital. Patients under 45 years old, those with chronic respiratory diseases or infections, individuals with unknown vaccination status or who were unvaccinated, and those whose HRCT chest reports were unavailable or taken more than 14 days after vaccination

were excluded from the study (Figure-1). Patients were categorized into two groups based on the type of COVID-19 vaccine received: Group 1 received COVAXIN (BBV152 vaccine), and Group 2 received COVISHIELD (ChAdOx1-S vaccine)



2.3 Data collection:

All necessary information was extracted from the selected case sheets using a semi-structured abstraction form comprising three sections:

- A: Demographic details, including MRD number, age, gender, and history of comorbid illnesses.
- B: Patient's vaccination history, detailing the type of COVID-19 vaccine administered and the number of doses received (one dose for partial vaccination, two doses for full vaccination).
- C: Patient's CORADS (COVID-19 Reporting and Data System) and CT Severity Scores (CTSS) obtained from their HRCT lung report.

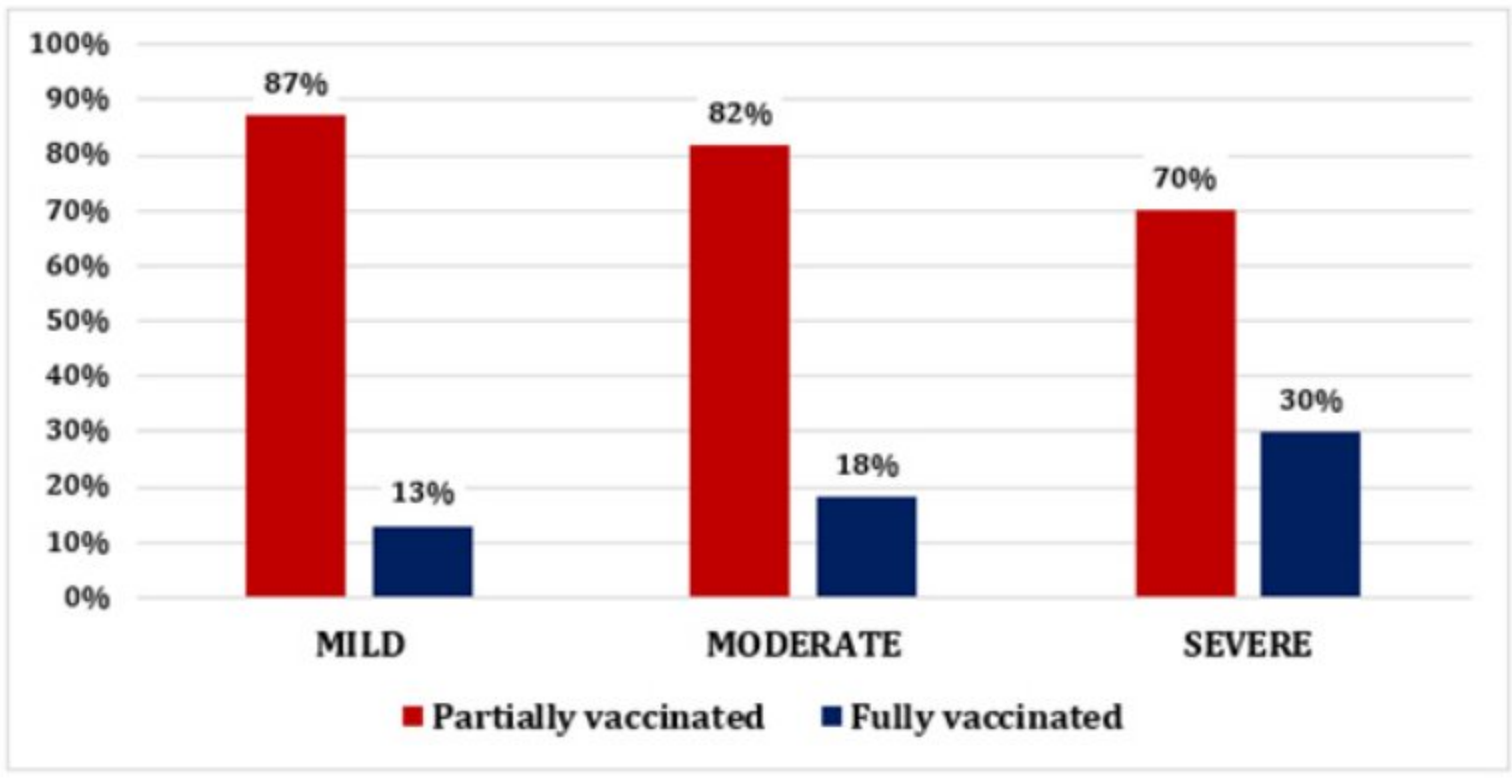
Given that CT imaging provides a direct and objective assessment of lung parenchymal involvement compared to non-specific inflammatory markers, the severity of lung involvement was categorized using the CT severity score based on the protocol for COVID-19 management - revised version 2.1, as issued by AIIMS on May 3, 2021 [11]. According to this classification, CTSS 8 indicated

mild lung involvement, CTSS 9–15 indicated moderate lung involvement, and CTSS >15 indicated severe lung involvement [12].

2.4 Data analysis:

The raw data collected was entered into Microsoft Excel 2019. Analysis was conducted using SPSS version 20 software, which included both descriptive and inferential statistics. Descriptive statistics such as frequencies and percentages were used for categorical variables, while means and standard deviations were calculated for continuous variables.

To determine associations between vaccinated COVID-19 patients and the severity of their illness based on explanatory variables, Fisher's exact test and binary logistic regression were employed. The significance level for all tests was set at 5%, with associations considered significant for P values less than 0.05.



3. RESULTS:

3.1 Characteristic of COVID-19 patients:

In this retrospective study, 204 vaccinated patients diagnosed with COVID-19 were admitted to a designated COVID-19 facility. The mean age of the participants was 61.8 ± 9.8 years, with more than half (52.7%) falling into the 61 years or older age group. The majority of participants (57.5%) were men. Among the vaccinated patients, 63.7% received the ChAdOx1-S vaccine (COVISHIELD) and 36.3% received the BBV152 vaccine (COVAXIN). A significant proportion (82.6%) were partially vaccinated (received one dose). Regarding CT severity, a higher percentage of partially vaccinated patients (6.9%) showed high severity compared to fully vaccinated patients (2.9%), regardless of the vaccine type (Figure-2). Among all vaccinated individuals, only 9.8% had severe disease with a CT severity score of 15 or above, based on their HRCT lung reports (Table-1).

Table -1: Distribution of demographic profile, vaccination status and severity of illness among COVID-19 patients (N=204).

VARIABLE		FREQUENCY N	PERCENTAGE %
AGE	45-60 YEARS	96	47.1
	61& ABOVE YEARS	108	52.9
GENDER	FEMALE	88	42.5
	MALE	118	57.5
CO-MORBIDITY	NO	132	64.7
	YES	72	35.3
TYPE OF VACCINE	COVIDSHIELD	130	63.7
	COVAXIN	74	36.3
DOSE OF VACCINE	PARTIALLY VACCINATED	168	82.4
	FULLY VACCINATED	36	17.6

3.2 Association:

Table 2 presents the findings of the Fisher exact test analysing the association between COVID-19 patient demographics, vaccination status, and HRCT lung results. The analysis revealed statistically significant differences in CT severity scores between male and female patients ($p=0.001$), with higher severity observed among male patients. Similarly, patients with a history of comorbidities exhibited significantly more severe lung involvement compared to those without comorbidities.

Furthermore, fully vaccinated patients, regardless of the vaccine type, showed less severe lung involvement than partially vaccinated patients, a difference that was statistically significant. Specifically, the study highlighted that patient who received the BBV152 vaccine had lower severity of lung involvement (1%) compared to those who received the ChAdOx1-S vaccine (8.8%).

Table- 2: Associated between CT severity score of HRCT lung report and demographic factors & vaccination status among COVID-19 patients.(N=204)

VARIABLE		CT SEVERITY SCORE CATEGORY			FISHER'S EXACT TEST VALUE	P-VALUE
		MILD (<8)	MODERATE (9-15)	SEVERE (>15)		
AGE	45-60 YEARS	32(15.7%)	58(28.4%)	6(2.9%)	3.237	0.189
	61& ABOVE YEARS	28(13.7%)	66(32.4%)	14(6.9%)		
GENDER	MALE	38(18.6%)	62(30.4%)	18(8.8%)	13.075	0.001***
	FEMALE	22(10.8%)	62(30.4%)	2(1%)		
COMORBIDITY	NO	46(22.5%)	86(42.2%)	0	43.217	0.001***
	YES	14(.9%)	38(18.6%)	20(9.8%)		
TYPE OF VACCINE	COVIDSHIELD	50(24.5%)	62(30.4%)	18(8.8%)	26.989	0.001***
	COVAXIN	10(4.9%)	62(30.4%)	2(1%)		
COVIDSHIELD	PARTIALLY VACCINATED	48(36.9%)	54(41.5%)	12(9.2%)	9.446	0.007**
	FULLY VACCINATED	2(1.5%)	8(6.2%)	6(4.6%)		
COVAXIN	PARTIALLY VACCINATED	4(5.4%)	48(64.9%)	2(2.7%)	5.890	0.037*
	FULLY VACCINATED	6(8.1%)	14(18.9%)	0		
SIGNIFICANT *P-VALUE<0.05, **P-VALUE<0.01, ***P-VALUE<0.001						

3.3 Regression:

Binary logistic regression was utilized to examine the relationship between the severity of lung involvement based on HRCT reports and the type of COVID-19 vaccination and doses administered (Table 3). The overall regression model demonstrated statistical significance with a Nagelkerke R^2 ranging between 7% to 9%.

Patients who received the BBV152 vaccine exhibited lower levels of lung involvement compared to those who received the ChAdOx1-S vaccine, and this difference was statistically significant. Moreover, individuals who were fully vaccinated (received two doses) with the ChAdOx1-S vaccine had a 1.6 times lower likelihood of experiencing severe illness compared to those who were partially vaccinated (received one dose), which was also statistically significant.

Table -3: Relationship between severity of lung involvement based on HRCT report and vaccination status among COVID-19 patients by using Binary Linear Regression.

VARIABLE		B	Exp B	SE	95% Confident interval for Exp B		P-value (<0.05)
					Lower	Upper	
TYPE OF VACCINE	COVAXIN	Ref					
	COVIDSHIELD	-1.755	0.173	0.761	0.039	0.767	0.021***
	CONSTANT	3.584	36.00	0.717			0.001***
COVAXIN	FULLY VACCINATED	Ref					
	PARTIALLY VACCINATED	17.94	62133.62	8987.42	0.001	0	0.998
	CONSTANT	-21.2	0.001	8987.42			0.998
COVIDSHIELD	FULLY VACCINATED	Ref					
	PARTIALLY VACCINATED	1.629	5.100	0.600	1.574	16.525	0.007***
	CONSTANT	0.511	1.667	0.516			0.323
Dependent reference group: Mild to moderate lung involvement (CTSS<15)							
*Reference group SIGNIFICANT *P-VALUE<0.05, **P-VALUE<0.01, ***P-VALUE<0.001							

4. DISCUSSION:

This study examined COVID-19 patients aged 45 years and older who received vaccination, aiming to assess how the severity of lung involvement, as determined by HRCT reports, correlates with the effectiveness of two commonly used vaccines. The age group was chosen based on Indian government guidelines prioritizing vaccination for those 45 and older due to higher COVID-19 severity in older adults [13]. The study participants had an average age of 61.8 ± 9.8 years, with more than half (52.5%) aged 61 years or older. However, there was no statistically significant link found between age and disease severity, consistent with findings from other diverse populations [14].

The study noted significantly higher disease severity among males (8.8%) compared to females (1%), which aligns with previous research by Kushwaha et al., Jin et al., and Betron et al. This difference may be attributed to behaviours such as smoking and biological factors affecting immune responses [17-19]. Comorbidities also played a critical role in disease severity, confirming previous research on their impact on COVID-19 progression [14,20,21].

Furthermore, the study highlighted that patient who received two doses

of either the BBV152 or ChAdOx1-S vaccine exhibited notably lower CT severity scores compared to those who received only one dose. This finding is consistent with studies conducted in other parts of India [22,23], underscoring the importance of completing the full vaccination schedule to reduce the risk of severe illness.

A noteworthy finding was the significantly higher effectiveness of the BBV152 vaccine compared to the ChAdOx1-S vaccine among fully vaccinated individuals, similar to findings reported by Fiolet et al. This difference may be attributed to the BBV152 vaccine's focus on the nucleocapsid protein, potentially offering better protection against prevalent mutated variants in the study region [24,25,26,27].

5. CONCLUSION:

This study demonstrates that both vaccines were highly effective (>90%) in preventing severe disease after two doses. When comparing the two vaccines, the BBV152 vaccine showed slightly greater effectiveness than the ChAdOx1-S vaccine in preventing severe forms of COVID-19.

5.1 Limitations & Recommendations:

This retrospective study, with its limited participant numbers, suggests the need for larger, longitudinal studies to comprehensively understand the natural progression of the disease and the vaccine's effectiveness against it. The current study classified participants into mild, moderate, and severe categories based on HRCT lung reports. Future research should consider incorporating clinical and serological parameters to provide a more detailed exploration of the disease process.

REFERENCES:

1. WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020 [Internet]. [cited 2023 May 6]. -19-11-march-2020

2. Chang, D., Chang, X., He, Y. et al. The determinants of COVID-19 morbidity and mortality across countries. *Sci Rep 12,* 5888 (2022). DOI: 10.1038/s41598-022-09783-9.

3. WHO-EUA-qualified-covid-vaccines.pdf [Internet]. [cited 2023 May 6].

4. India – COVID19 Vaccine Tracker [Internet]. [cited 2023 May 6].

5. Harder T, Külper-Schiek W, Reda S, et al. Effectiveness of COVID-19 vaccines against SARS-COV-2 infection with the delta (b.1.617.2) variant: Second interim results of a living systematic review and meta-analysis, 1 January to 25 August 2021. *Eurosurveillance*. 2021;26(41). Doi: 10.2807/1560-

7917.ES.2021.26.41.2100920
6. India's "Covaxin" vaccine shows high efficacy against COVID-19 infections in phase 3 trial [Internet]. [cited 2023 May 6].
7. Tartof SY, Slezak JM, Fischer H,et al. Effectiveness of mRNA BNT162b2 COVID-19 vaccine up to 6 months in a large integrated health system in the USA: a retrospective cohort study. *The Lancet*. 2021 Oct 16th.
8. Hadizadeh, N., Naderi, M., Khezri, J. et al. Appraisal of SARS-CoV-2 mutations and their impact on vaccination efficacy: *an overview. J Diabetes Metab Disord 21*, 1763–1783 (2022). Doi: 10.1007/s40200-022-01002-6
9. COVAXIN - India's First Indigenous Covid-19 Vaccine | Bharat Biotech [Internet]. [cited 2023 May 6].
10. Press statement by the Drugs Controller General of India (DCGI) on restricted emergency approval of COVID-19 virus vaccine. Press Information Bureau. Government of India; [cited 2023 May 6].
11. AIIMS - Version 2.1 - Protocol for COVID-Management - Dt 03.05.21. pdf [Internet]. [cited 2023 May 6].
12. Francone M, Iafrate F, Masci GM, et al. Chest CT score in COVID-19 patients: Correlation with disease severity and short-term prognosis. *European Radiology*. 2020;30(12):6808–17. DOI: 10.1007/s00330-020-07033-y
13. Guideline for COVID-19 vaccination of children between 12-14 years of age [Internet]. MoHFW Home. Government of India; 2022 [cited 2023 May 6].
14. Sharma R, Thakker V, Sharma RB, et al. Effect of vaccination on the HRCT profile of COVID-19 patients – a single-centre experience. *Journal of Family Medicine and Primary Care*. 2022;11(6):2938. Doi: 10.4103/jfmpc.jfmpc_2355_21
15. Boehmer TK, DeVies J, Caruso E et al. Changing age distribution of the COVID-19 pandemic – United States, May–August 2020 [Internet]. *Centres for Disease Control and Prevention*; 2020 [cited 2023 May 22].
16. Nicoli F, Solis-Soto MT, Paudel D, et al. Age-related decline of de Novo T cell responsiveness as a cause of covid-19 severity. *GeroScience*. 2020;42(4):1015–9. Doi: 10.1007/s11357-020-00217-w
17. Kushwaha S, Khanna P, Rajagopal V,et al. biological attributes of age and gender variations in Indian covid-19 cases: *A Retrospective Data Analysis. Clinical Epidemiology and Global Health*. 2021;11:100788. Doi: 10.1016/j.cegh.2021.100788
18. Jin J-M, Bai P, He W, et al. Gender differences in patients with covid-19: Focus on severity and mortality. *Frontiers in Public Health*. 2020;8. Doi: 10.3389/fpubh.2020.00152
19. Betron M, Gottert A, Pulerwitz J,et al. Men and COVID-19: Adding

a gender lens. *Glob Public Health*. 2020 Jul;15(7):1090-1092. Doi: 10.1080/17441692.2020.1769702

20. Gupta N, Kaur H, Yadav P, et al. *Clinical characterization and genomic analysis of covid-19 breakthrough infections during second wave in different states of India*. 2021 Sep 7;13(9):1782. Doi: 10.3390/v13091782

21. Vaidiyanathan B, Dhanger S, Raajesh J, et al. To determine the clinical efficacy of COVID vaccine in post-vaccinated individuals with severe pneumonia in preventing ICU mortality in a COVID designated Tertiary Care Centre: A retrospective study. *Archives of Anaesthesia and Critical Care*. 2022;8(3):208-212.

22. Gurumurthy B, Das S, Shetty S, et al. CT severity score: an imaging biomarker to estimate the severity of COVID-19 pneumonia in vaccinated and non-vaccinated population. *Egyptian Journal of Radiology and Nuclear Medicine*. 2022;53(1); 88. Doi: 10.1186/s43055-022-00768-2

23. Verma A, Kumar I, Singh PK, et al. Initial comparative analysis of pulmonary involvement on HRCT between vaccinated and non-vaccinated subjects of COVID-19. *Eur Radiol*. 2022;32(6):4275–83. Doi: 10.1007/s00330-021-08475-8

24. Fiolet T, Kherabi Y, MacDonald C-J,et al. Comparing covid-19 vaccines for their characteristics, efficacy and effectiveness against SARS-COV-2 and variants of concern: A narrative review. *Clinical Microbiology and Infection*. 2022;28(2):202–21. Doi: 10.1016/j.cmi.2021.10.005

25. Das S, Kar SS, Samanta S,et al. Immunogenic and reactogenic efficacy of Covaxin and Covishield: *A comparative review. Immunologic Research*. 2022;70(3):289–315. Doi: 10.1007/s12026-022-09265-0

26. Singh DD, Parveen A, Yadav DK. SARS-COV-2: Emergence of new variants and effectiveness of vaccines. *Frontiers in Cellular and Infection Microbiology*. 2021;11: 777212. Doi: 10.3389/fcimb.2021.777212

27. Mohammadi M, Shayestehpour M, Mirzaei H. The impact of Spike mutated variants of SARS-cov2 [alpha, beta, gamma, Delta, and lambda] on the efficacy of subunit recombinant vaccines. *The Brazilian Journal of Infectious Diseases*. 2021;25(4):101606. Doi: 10.1016/j.bjid.2021.101606